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may be made. However, except for research exempted or waived under § 745.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§ 745.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

§ 745.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.

The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ 745.121 [Reserved]

§ 745.122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

10 CFR Ch. III (1–1–09 Edition)

§ 745.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to Federal regulation).

§ 745.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

PART 760—DOMESTIC URANIUM PROGRAM

§ 760.1 Uranium leases on lands controlled by DOE. (Domestic Uranium Program Circular No. 760.1, formerly (AEC) Domestic Uranium Program Circular 8, 10 CFR 60.8).

(a) *What this section does.* This section sets forth regulations governing the issuance of leases to permit the exploration for and mining of deposits containing uranium in public lands withdrawn from entry and location under the general mining laws for use of

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DOE, and in certain other lands under DOE control.

(b) *Statutory authority.* The Atomic Energy Act of 1954, as amended (68 Stat. 919, 42 U.S.C. 2011 *et seq.*) is the authority for this section.

(c) *Who may hold leases.* Only parties who are (1) citizens of the United States; (2) associations of such citizens; or (3) corporations organized under the laws of the United States or territories thereof, are eligible lessees under this section. Persons under 21 years of age or employees of DOE are not eligible.

(d) *Issuance of leases through competitive bidding.* Except under special circumstances as provided in paragraph (u) of this section, each lease will be offered through competitive bidding and, except as otherwise provided in this paragraph (d), will be issued to the acceptable bidder offering the highest bid. The bid may be on a cash bonus, royalty bonus, or other basis as specified in the invitation to bid. Invitations to bid on some of the lands may be limited to small business concerns as defined by the Small Business Administration, and such invitations may limit the number of leases to be awarded to each bidder. In such cases DOE will accept those bids which, in relation to other bids received pursuant to the invitation, are most advantageous to the Government. Before any lease is awarded, DOE may require high bidders to submit a detailed statement of the facts as to such matters as their experience, organization, and financial resources. DOE reserves the right to reject any and all bids.

(e) *Solicitation of bids.* Announcements of the availability of invitations to bid for a lease will be publicly posted and published. Copies of such announcements will also be mailed to parties who submit to DOE's Grand Junction, Colorado, Office subsequent to publication in the FEDERAL REGISTER of this (DOE) Domestic Uranium Program Circular 760.1, written requests that their names be placed on a mailing list for receipt of such announcements. The invitations containing information for preparation and submission of bids will be available at the Grand Junction Office, and will be mailed only on specific written request, following announcement of their

availability. Invitations will specify the land to be leased, the basis on which bids are to be submitted, the amount of the monetary deposit which must be transmitted with the bid, the place and time the bids will be publicly opened, the term, royalty and other payments, performance requirements, and other payments, performance requirements, and other conditions which will become a part of the lease. In addition, data which have been assembled pertaining to the lands to be leased will be available for public inspection at the Grand Junction Office; copies will also be available for purchase.

(f) *Bidding requirements; deposits.* All bids must be filed at the place and prior to the time set forth in the invitation. Each bid must be sealed and accompanied by a deposit, in the form of a certified check, cashier's check, or bank draft, in an amount as specified in the invitation to bid. Deposits of unsuccessful bidders will be returned. If the bidder is an individual, he must submit with his bid a statement of his citizenship and age. If the bidder is an association (including a partnership), the bid shall be accompanied by a certified copy of the articles of association together with a statement as to the citizenship and age of its members. If the bidder is a corporation, evidence that the officer signing the bid had authority to do so and a statement as to the State of incorporation shall also be submitted.

(g) *Awarding of lease.* Following public opening of the bids, DOE, subject to the right to reject any and all bids, will determine the successful bidder. In the event the highest acceptable bids are tie bids, a public drawing will be held by DOE to determine the successful bidder. After notice of award and within the time period prescribed in the invitation, the successful bidder shall execute and return to DOE three (3) copies of the lease and shall remit payments due as prescribed in the invitation. Should the successful bidder fail to execute the lease, or make payments as required, in accordance with the terms of the invitation, or fail to otherwise comply with applicable regulations, he may be required to forfeit any payments previously made, and lose

any further right or interest in the lease. In such event, DOE may offer the lease to the next highest acceptable bidder, reoffer the lease for bidding, or take such other action as appropriate. If the awarded lease is executed by the bidder through an agent, evidence of authorization must be submitted.

(h) *Dating of lease.* A lease issued under this section will ordinarily be effective as of the date it is signed on behalf of DOE.

(i) *Term of lease.* A lease shall be for the period specified in the invitation to bid. When deemed desirable by DOE, the lease will provide that the lease term may be extended at the option of the lessee for a specified period and upon stipulated conditions.

(j) *Payments to DOE under lease.* Royalty payments shall be specified in the invitation to bid; base royalty, minimum royalty, advance royalty, and rental payments, or a combination thereof may be required.

(k) *Title to unshipped ore.* DOE, unless it approves otherwise, reserves all right and title to property in and to all ores and other uranium- or vanadium-bearing material not removed from the leased premises within 60 days after expiration or other termination of the lease. Unless DOE approves otherwise, all material mined from the leased premises and not marketed by the lessee shall remain on the leased premises.

(l) *Environmental controls.* Each lease will contain such provisions as may be deemed necessary by DOE with respect to the lessee's use of the leased lands. DOE may require periodic submission of plans for exploration and mining activities including provisions for control of environmental impact. The lessee will be required to conduct operations so as to minimize adverse environmental effects, to comply with all applicable State and Federal statutes and regulations and to the extent stipulated in the lease agreement, will be held responsible for maintenance or rehabilitation of affected areas in accordance with plans submitted to and approved by DOE.

(m) *Performance requirements.* A lease shall require that exploration, development, and mining activities, as appropriate, be conducted on the leased

premises with reasonable diligence, skill, and care as required to achieve and maintain production of uranium ore at rates consistent with good and safe mining practice and with market conditions.

(n) *Health and safety requirements.* A lease (1) shall require that exploration, development, and mining activities, as appropriate, be conducted on the leased premises with due regard for the health and safety of those involved, and (2) shall include appropriate measures for the control of radiation exposure in the mines.

(o) *Lessee's records.* Leases shall provide that the lessee keep and make available to DOE such records as DOE deems necessary for the administration of the lease and its leasing program.

(p) *Rights of DOE.* DOE reserves the right to enter upon the leased property and into all parts of the mine for inspection and other purposes. DOE also reserves the right to grant to other persons easements or rights of way upon, through, or in the leased premises. DOE and the Comptroller General of the United States or any of his duly authorized representatives shall, until the expiration of 3 years after termination or expiration of lease, have access to and the right to examine any directly pertinent books, papers, and records of the lessee involving transactions related to the lease.

(q) *Relinquishment of leases.* A lease may be surrendered by the lessee upon filing with and approval by DOE of a written application for relinquishment. Approval of the application shall be contingent upon the delivery of the leased premises to DOE in a condition determined to be satisfactory to DOE. The lessee shall continue to be liable for the payment of all royalty and other debts due DOE.

(r) *Assignment of leases.* Any transfer of a lease or any interest therein or claim thereunder, will not be recognized unless and until approved by DOE in writing. Ordinarily, DOE will not approve any transfer of a lease which involves overriding royalties or deferred payments of any kind to the transferor.

(s) *Cancellation.* Any lease may be cancelled by DOE whenever the lessee fails to comply with the provisions of

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the lease. Failure of DOE to exercise its right to cancel shall not be deemed a waiver thereof.

(t) *Form of lease.* Leases will be issued on forms prescribed by DOE.

(u) *Noncompetitive leases.* Under special circumstances, where DOE believes it to be in the best interest of the Government, DOE at its discretion may award or extend leases on the basis of negotiation.

(v) *DOE decisions.* All matters connected with the issuance and administration of leases will be determined by DOE whose decisions shall be final and conclusive.

(w) *Definitions.* DOE as used in this section means the United States Department of Energy or its duly authorized representative or representatives.

(x) *Multiple use of land.* Leases issued under this section shall provide that operations under them will be conducted so as not to interfere with the lawful operations of any third party having a lease, permit, easement, or other right or interest in the premises.

(y) *Compliance with State and Federal regulations.* Every lease shall provide that the lessee is required to comply with all applicable State and Federal statutes and regulations.

(Secs. 66, 161, 68 Stat. 933, 948, as amended; 42 U.S.C. 2096, 2201)

[41 FR 56783, Dec. 30, 1976]

PART 765—REIMBURSEMENT FOR COSTS OF REMEDIAL ACTION AT ACTIVE URANIUM AND THORIUM PROCESSING SITES

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765.30 Reimbursement of costs incurred in accordance with a plan for subsequent remedial action.

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AUTHORITY: 42 U.S.C. 2296a *et seq.*

SOURCE: 59 FR 26726, May 23, 1994, unless otherwise noted.

Subpart A—General

§ 765.1 Purpose.

The provisions of this part establish regulatory requirements governing reimbursement for certain costs of remedial action at active uranium or thorium processing sites as specified by Subtitle A of Title X of the Energy Policy Act of 1992. These regulations are authorized by section 1002 of the Act (42 U.S.C. 2296a-1), which requires the Secretary to issue regulations governing the reimbursements.

§ 765.2 Scope and applicability.

(a) This part establishes policies, criteria, and procedures governing reimbursement of certain costs of remedial action incurred by licensees at active uranium or thorium processing sites as a result of byproduct material generated as an incident of sales to the United States.

(b) Costs of remedial action at active uranium or thorium processing sites are borne by persons licensed under section 62 or 81 of the Atomic Energy Act (42 U.S.C. 2092, 2111), either by NRC or an Agreement State pursuant to a counterpart to section 62 or 81 of the Atomic Energy Act, under State law, subject to the exceptions and limitations specified in this part.

(c) The Department shall, subject to the provisions specified in this part, reimburse a licensee, of an active uranium or thorium processing site for the portion of the costs of remedial action as are determined by the Department to be attributable to byproduct material generated as an incident of sales to